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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,964	10/12/2000	Geert Maertens	2551-48	5719

7590

08/09/2002

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/686,964

Applicant(s)

MAERTENS ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36- 77 is/are pending in the application.
- 4a) Of the above claim(s) 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36- 41, and 44- 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the Response from Applicant filed 2 July 2002.

Claims 37- 41, and 44- 77 are pending in this application.

#### ***Election/Restrictions/ Supplemental Response***

Applicant has canceled all the claims of the application as filed and submitted new claims and an election of Group I. The claims as rewritten recite material that was subject to restriction including an election of a SEQ ID# in the Restriction Requirement (paper 6). The traversal is on the ground(s) that "examination of all the pending claims would not be an undue burden on the Examiner." This is not found persuasive because each sequence variation constitutes a distinct chemical structure and not obvious over others as claimed. As stated in the Restriction mailed 2/13/02 an election of one sequence ID# would be required if an inventive group including them was elected.

Applicant has responded to the letter of 5/31/02 with an election of SEQ# 18 with traverse. The traverse on the grounds that the O.G. notice allows 10 sequences not correct. The notice allows for up to ten sequences; however, the current policy of the office is to search one sequence per application. For further clarification, please contact James Housel whose phone number is below.

All sequence ID#s except #18 and claims 42 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in the EPO on 4/17/1998 (EPO 98870087.8), paper #3. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. It appears that WO 99/54735, the basis of the International Search Report submitted with this application, could be used as a priority document. The first line of the specification must be updated to reflect the claimed priority.

Applicant is advised that the filing date of this instant application is the earliest priority date for this application.

### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Claim Objections***

Claim 63 contains the trademark/trade name Empigen. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a zwitter ionic detergent and, accordingly, the identification/description is indefinite.

#### ***Claim Rejections - 35 USC § 112***

Claims 36- 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is not clear because it is not clear what "solid phase carrying," means. It is not clear what the metes and bounds of the peptide variations in claims 44- 49 are. The claims recite "protein or part thereof containing either" followed by an "or " and then another "or" and it is not clear if the first group is to be taken all or none or part in combination with the remaining residues. Also, it is not clear if these numbers refer to amino acid positions and if so, then what is the reference point for these positions. It is also not clear if these refer to changes or to a definition of fragments and function.

Claim 76 recites the limitation "said solid phase" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is also not clear what the method is in this claim. It is not clear what "HCV, NS3" is supposed to mean. Also, there is no clear result method step and it is not clear if the kit is required to practice the method, "Said kit" in line three lacks antecedent basis, it appears that there are two incomplete methods in the claim, and it is not clear if the NS3 protein is in the kit or in the sample to be detected.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76 and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunoassay kit, does not reasonably provide enablement for all methods of detecting anti-HCV NS3 antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are drawn to any method not necessarily using the kit of claim 36.

Due to the large quantity of experimentation necessary to determine all possible NS3 proteins to use with the solid support, the lack of direction/guidance presented in the specification regarding how the claimed method is carried out, the absence of

working examples directed to the claimed method, and the breadth of the claims which fail to recite limitations of a specific antigen and kit, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 76 and 77 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for a method that comprises the use of two methods at the same time to detect anti-HCV NS3 antibody.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36- 41, and 50- 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Figard (US Patent 5616460).

Figard discloses an immunoassay comprising HCV NS3 antigen bound to a solid support to detect antibodies to HCV- NS3 using reducing agent and biological detergent(Example 1). The step at which reducing agent is added and the step of sulphonation/desulphonation are method steps and are not encompassed in the claimed product. The use of fusion protein and type of assay in kit are inherent to the product and obvious to those skilled in the art.

Claims 36- 41, and 50- 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel (US 6036579).

Seidel teaches an immunoassay NS3 HCV antigen bound to a solid support and the advantage of using a reducing agent to aid in detection (Example 5). The step at which reducing agent is added and the step of sulphonation/desulphonation are method steps and are not encompassed in the claimed product. The use of fusion protein and type of assay in kit are inherent to the product and obvious to those skilled in the art.

It is noted by the Examiner that should Applicant perfect priority to the earlier filed applications, this art would still apply under 102(e).

Claim 39 consisting of SEQ ID # 18 and claims 44- 49 are rejected under 35 U.S.C. 102(b) as being anticipated by LEROUX-ROELS (WO 9512677 A3, claim 5 and Fig. 6).

The sequence is taught by LEROUX-ROELS. For this claimed protein to be expressed it must contain an initiation methionine and therefore it would be obvious to one skilled in the art to add a methionine. The mutations alternate residues listed in the claims are anticipated by the alternative residues listed in Fig. 6.

**Conclusion**


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
August 7, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
1600